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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,269	09/23/1999	RANDALL S. ALBERTE	CEA-004.01	9298

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EXAMINER

YAMNITZKY, MARIE ROSE

ART UNIT	PAPER NUMBER
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1774

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,269

Applicant(s)

ALBERTE ET AL.

Examiner

Marie R. Yamnitzky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-30,32-39,42-44,47-63,66,68,70-74 and 89-91 is/are pending in the application.
4a) Of the above claim(s) 27,28 and 34-37 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4-6,9-26,29,30,32,33,38,39,42-44,47-63,66,68,70-74 and 89-91 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 03312005.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 08, 2004 has been entered.

2. Applicant's amendment received November 08, 2004 amends claims 1, 5, 12, 13, 17, 21, 22, 29, 39, 43, 50, 51, 55, 59 and 60, cancels claims 2, 3, 7, 8, 31, 40, 41, 45, 46, 67 and 69, and provides substitute pages for pages 9-12, 22 and 24 of the specification.

Claims 1, 4-6, 9-30, 32-39, 42-44, 47-63, 66, 68, 70-74 and 89-91 are pending.

3. The objection to the disclosure, for the informalities noted in the Office action mailed August 27, 2003, is overcome by the substitute specification pages received November 08, 2004.

The rejection of claims 31 and 67 under 35 U.S.C. 112, 1st paragraph (for failing to comply with the written description requirement), as set forth in the Office action mailed May 05, 2004, is rendered moot by claim cancellation.

The rejection under 35 U.S.C. 112, 2nd paragraph, as set forth in the Office action mailed May 05, 2004, is rendered moot in part by claim cancellation, overcome in part by claim amendment, and withdrawn in part in consideration of applicant's arguments received November 08, 2004 (regarding the issue of 4-(1-methyl-1-phenylethyl)phenyl). Remaining issues are set forth later in this action.

As noted in the Advisory action mailed December 08, 2004, the provisional obviousness-type double patenting rejection over claims of copending Application No. 09/405,299 is overcome by the Terminal Disclaimer received November 08, 2004.

4. The claims remain subject to an election of species. In the reply filed on May 14, 2001, applicant elected the species of a compound of general structure 1, applied to the surface of a medical device, wherein X represents -OH, Y represents O and Z represents an optionally substituted aryl. Of the pending claims, claims 1, 4-6, 9-26, 29, 30, 32, 33, 38, 39, 42-44, 47-63, 66, 68, 70-74 and 89-91 read on the elected species. (Claims dependent from claim 39 which further limit the article are all considered to read on the elected species since, for claim 39 and dependents, the article pertains to the intended use of the claimed coating.)

Claims 27, 28 and 34-37 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 14, 2001.

5. Claims 1, 4-6, 9-26, 29, 30, 32, 33, 38, 39, 42-44, 47-63, 66, 68, 70-74 and 89-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific systems and coatings demonstrated by the examples to have anti-fouling capabilities as required by the present claims, does not reasonably provide enablement for a system of the scope as claimed in present claim 1 and dependents or a coating of the scope as claimed in present claim 39 and dependents wherein the terms "system", "biofilm resistant surface" and "coating"

encompass numerous structures/compositions, the term “anti-fouling” encompasses a variety of possible modes of action against numerous possible organisms, and the general structure for the compound as defined in the independent claims and some of the dependent claims encompasses numerous compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In light of the specification, the terms “system” and “biofilm resistant surface” encompass a very large group of articles/surfaces including such disparate “systems” as food processing equipment, heart valves, tampons and toilets. For example, see page 5, lines 8-17, p. 9, l. 5-7, p. 15, l. 16; p. 15, l. 26-p. 16, l. 2, p. 16, l. 23-p. 17, l. 10, p. 18, l. 6-14, p. 18, l. 20-p. 19, l. 10 and p. 25, l. 9-p. 26, l. 27. In light of claim 29, it appears that the presently claimed system even encompasses plants.

In light of the specification, the term “coating” encompasses gas, vapor, liquid, paste, semi-solid or solid, examples of which include polishes, surface cleaners, caulks, adhesives, finishes, paints, waxes and polymerizable compositions (e.g. see p. 14, l. 19-22).

In light of the specification, an “anti-fouling” compound is one that impairs, inhibits, prevents or retards the attachment and/or growth of organisms such as bacteria, fungi, viruses and protists (e.g. see p. 12, l. 16-18, p. 13, l. 23-24 and p. 18, l. 15-19).

The compounds as defined in the present independent claims and some of the dependent claims encompass numerous compounds.

Accordingly, the present system claims encompass objects as diverse as food processing equipment, heart valves, tampons and toilets, and the present coating claims encompass any gas, vapor, liquid, paste, semi-solid or solid, wherein the system or coating comprises at least one compound selected from numerous compounds encompassed by the general structures defined in the claims that would impair, inhibit, prevent or retard the attachment and/or growth of organisms such as bacteria, fungi, viruses and/or protists. Clearly, the claims are extremely broad.

The present specification provides data demonstrating anti-fouling capabilities of only a few compounds within the scope of the present claims, and demonstrates the anti-fouling characteristics of only a few systems and coating. The limited data presented in the specification are insufficient to demonstrate any predictability with respect to how each of the numerous compounds encompassed by the general structures defined in the present claims would function in an anti-fouling capacity against any one of thousands of possible organisms such as bacteria, fungi, viruses and/or protists if used in/on any one of the numerous possible diverse surfaces/systems contemplated by the present specification and encompassed by the present claims. Accordingly, it is the examiner's position that it would require undue experimentation on the part of one of ordinary skill in the art at the time of the invention to make and use the invention commensurate in scope with the present claims.

Data pertaining to four compounds are set forth in the specification. One of the tested compounds (zosteric acid) does not meet the limitations of the anti-fouling compound required for any of the pending claims. Two of the tested compounds (methyl sulfate and octyl

sulfate) meet of the limitations of the anti-fouling compound required for present claim 1 and some of the claims dependent therefrom, but do not meet the limitations of the anti-fouling compound required for present claim 39 and dependents. Only one of the tested compounds (4-t-pentylphenyl chlorosulfate) meets the limitations of the anti-fouling compound required for each of the pending claims, and the single example presented for that compound pertains to sea urchin fertilization.

Even in the case where the compounds required for the claimed system or coating are limited to a relatively small number of compounds, the claims are still broader in scope than the enabling scope of the disclosure because limitations such as the "effective amount" are defined only in reference to a variety of potential applications. It is the examiner's position that the data presented in the specification are insufficient to demonstrate predictability even with respect to the limited number of compounds defined, for example, in claims 24 and 62 (the system and coating claims that are most limited with respect to the anti-fouling compound), given the broad scope of systems, biofilm resistant surfaces, coating formulations, and anti-fouling capabilities encompassed by the present claim terminology. 4-t-pentylphenyl chlorosulfate is the only compound tested in the specification that is within the scope of the sixteen compounds defined by claim 24 and the twelve compounds defined by claim 62. It is not clear that the activity of 4-t-pentylphenyl chlorosulfate towards sea urchin fertilization is representative of all systems encompassed by claim 24 and all coatings encompassed by claim 62, or that the full scope of systems and coatings encompassed by these claims can be determined without undue

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experimentation based on the single sea urchin fertilization example using 4-t-pentylphenyl chlorosulfate.

6. Claims 51 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 53 allow Z to represent "heteroalkylphenyl", but a heteroalkyl substituent, in general, is not within the scope of possible substituents for Z as defined in claim 39, from which claims 51 and 53 depend. (Claim 39 does allow the substituent for Z to be trifluoromethyl, which is a specific heteroalkyl group. However, the recitation of "heteroalkylphenyl" in claims 51 and 53 provides for substituted phenyl groups other than trifluoromethylphenyl groups, and thus does not properly further limit the claimed subject matter.)

7. Applicant's arguments filed November 08, 2004 have been fully considered, along with the telephonic discussions on January 10, 2005 and February 04, 2005, but they are not persuasive with respect to the enablement issue.

Although the independent claims and various dependent claims have been narrowed with respect to the scope of compounds covered by general structure 1, general structure 1 as defined, for example, in independent claims 1 and 39 still covers a large variety of compounds. The limited number of examples set forth in the specification are insufficient to demonstrate that the

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anti-fouling capabilities of the various compounds towards the numerous organisms which might foul a system/surface are sufficiently predictable such that undue experimentation would not be required to determine the scope of systems encompassed by claim 1 and dependents, and the scope of coatings encompassed by claim 39 and dependents.

8. Miscellaneous:

The following is not an objection or rejection, it is merely brought to applicant's attention in case claims 1 and 39 have not been narrowed to the extent intended by applicant.

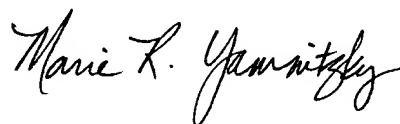
In the second line of the definition of Z in claim 1 and 39, "heteroaryl" has been deleted. However, Z may be optionally substituted $-(CH_2)_m-R_{80}$ in which m is in the range of 0 to 8, inclusive, and R_{80} is aryl, cycloalkyl, cycloalkenyl, heterocyclyl, or polycyclyl. Compounds in which Z is heteroaryl are encompassed by compounds in which Z is $-(CH_2)_m-R_{80}$, m is zero and R_{80} is heterocyclyl. A compound in which m is zero and R_{80} is polycyclyl also encompasses some compounds in which Z is heteroaryl. (Compounds in which Z is cycloalkenyl are also covered by present claims 1 and 39 when m is zero. Compounds in which Z is aryl or cycloalkyl are covered by the recitation of "cycloalkyl" and "aryl" in the first two lines of the definition of Z, as well as by $-(CH_2)_m-R_{80}$ when m is zero and R_{80} is cycloalkyl or aryl.)

9. Any inquiry concerning this communication should be directed to Marie R. Yamnitzky at telephone number (571) 272-1531. The examiner works a flexible schedule but can generally be reached at this number from 6:30 a.m. to 4:00 p.m. Monday, Tuesday, Thursday and Friday, and every other Wednesday from 6:30 a.m. to 3:00 p.m.

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The current fax number for Art Unit 1774 is (703) 872-9306 for all official faxes.
(Unofficial faxes to be sent directly to examiner Yamnitzky can be sent to (571) 273-1531.)

MRY
March 31, 2005

A handwritten signature in cursive script that reads "Marie R. Yamnitzky".

MARIE YAMNITZKY
PRIMARY EXAMINER

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